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To: Representative Mike Callton, Chairman  
House Health Policy Committee Members

From: Ryan Foster, Senior Director of Pharmacy Services  
Spectrum Health Hospital Group

Date: September 20, 2016

RE: SUPPORT: House Bill 5877

Good Morning Chairman Callton and House Health Policy Committee members. Thank you for the opportunity to speak about an issue that has negatively affected the way Spectrum Health and other hospital pharmacies across the state are delivering care to patients. I am Ryan Foster, Senior Director of Pharmacy Services at Spectrum Health. According to Michigan Law, I am one of Spectrum Health's "Pharmacists in Charge."

The controlled substance facility licenses for three of our outpatient facilities that are down the road from our main campus, were scheduled to expire on 6/30/16. Spectrum Health pharmacy attempted to renew the licenses for these locations twice at the end of May. The license renewals were rejected by LARA both times, indicating the licenses were not valid. This was prior to receiving an official letter from LARA regarding the options for resolution. For your reference, I have attached a copy of the letter to the written testimony.

On June 3, 2016, I was notified by the Michigan Health & Hospital Association (MHA) that these licenses would not be renewed because they were not in compliance with Michigan law and LARA had issued the licenses in error. The State suggested two options for resolution: (1) build and license a pharmacy at each location or (2) identify a physician to assume accountability for the Pyxis and the medication supply chain. However, as could be expected, identifying physicians willing to accept control and accountability for the large volume of controlled substances used at these locations was not easy. Physicians at these practices, although responsible for the medications administered to their patients, are not familiar, nor are they necessarily appropriate to manage the medication supply chain and logistics, let alone be responsible for controlled substance diversion monitoring.

Although Spectrum Health identified three separate physicians to assume control of these medications at the locations, the process by which these physicians were identified caused a great deal of unnecessary stress and diverted our leadership attention from more critical issues including our top priority, patient care. The timeline below in this

testimony briefly describes our experience with identifying a solution. To be respectful of committee member's time I will not be reading each step, just submitting the timeline as part of my testimony. I wanted to highlight a few items. To comply with the newly offered resolutions in less than a month since our licenses were set to expire, it took 15 Spectrum Health employees 54 hours of meeting time, and over \$87,000 (not including staff time).

Fortunately, Spectrum Health is a large system and is able to adapt to these changes despite the extra expense. I am unsure how the other 10 facilities whose licenses were issued in error by LARA and unable to be renewed in June 2016 handled this problem. There are 46 more licenses that will be affected in 2017 and some of those are small and rural facilities that do not have the resources or staff power of a large system like Spectrum. Today I am asking that you support House Bill 5877 so Pyxis machines are under the control and accountability of pharmacists which aligns with current practice and also will correct the licensing error.

### **Timeline of Events**

6/15/16: An initial leadership call was held, including 2 nurse managers, 2 site managers, the surgery medical director, senior pharmacy director, and 2 pharmacy managers. This purpose of this call was to discuss the issue of the licenses not being able to be renewed and the need to pursue one of the two options described above.

On June 20, Pharmacy leadership met with the Ambulatory Surgery Center leadership, including the Medical Director, to discuss the prescriber option. The physicians were not willing to assume control of the medications. Spectrum Health pharmacy had initially planned to build out and license individual pharmacies at each of these locations, however, due to building and time restraints, this option was determined to not be a feasible solution.

6/22/16: Given that physicians could not be readily identified to assume control of the medications, a leadership call with the Senior Vice President Clinical Operations, Senior Director Pharmacy, and Pharmacy Manager was held in order to develop a plan for moving forward.

6/23/16: A call with MHA and the Senior Pharmacy Director and Pharmacy Manager was held to discuss the challenges at Spectrum Health. At this point, the pharmacy was planning to pursue building out and licensing pharmacies at each location.

6/24/16: A leadership call was held with the Surgery Director, Surgery Operations Director, Medical Director, Nurse Manager, Senior Pharmacy Director, Pharmacy Manager to discuss the option of building out pharmacies at each location. On 6/23/16, locations were identified at each location for the pharmacies, however, obtaining the appropriate building permits would not be feasible given the licensure deadline. At this point, we made the decision to escalate to senior leadership. We were concerned about canceling scheduling surgeries and rescheduling patients.

**6/27/16: Leadership meeting with Vice President Surgical Services, Senior Pharmacy Director, Pharmacy Manager to discuss the feasibility of identifying physicians or canceling surgeries. This was a reiteration of the impasse we had reached.**

**6/28/16 9:30pm: Leadership meeting with Chief Operating Officer, Senior Vice President Clinical Operations, Vice President Surgical Services, Vice President Medical Affairs and Senior Director Pharmacy to discuss the licensure issue and the need for an expedient solution.**

**6/29/16 11:00am: A follow up leadership call with Senior Vice President Clinical Operations, Deputy General Counsel, Vice President Medical Affairs, Chief Operating Officer, Vice President Surgical Services, Senior Compliance Analyst, Senior Director Pharmacy. The real possibility of canceling scheduled cases was discussed at length should physicians not be identified.**

**6/29/16: Three physicians were identified and willing to complete the required license applications. Pharmacy Manager drives additional location licenses to Lansing in order for the applications to be processed in a timely manner and allow for Spectrum Health to continue to provide health care services at Ambulatory Surgery Centers.**

**6/29 4:00pm: Another leadership call with Senior Vice President Clinical Operations, Deputy General Counsel, Vice President Medical Affairs, Chief Operating Officer, Vice President Surgical Services, Senior Compliance Analyst, Senior Director Pharmacy was held to discuss the current state scenario.**

**6/30 11:00am: A final leadership call with Senior Vice President Clinical Operations, Deputy General Counsel, Vice President Medical Affairs, Chief Operating Officer, Vice President Surgical Services, Senior Compliance Analyst, Senior Director Pharmacy was held to discuss the final plan and determine a go forward plan. The licenses were reviewed and approved by the State and verified on LARA.**

The meetings described above demonstrate the high level attention this issue required. The table below describes the set up and maintenance costs associated with achieving this option for resolution.

<b>Set Up Costs</b>			
Drug Control License	South Pavilion / Endoscopy / Surgery	\$45 each	\$135
CS Additional Location	Dr. Dobbie	\$85 each	\$255
CS Additional Location	Drs. Young, Thamban	\$235 each	\$470
DEA Licenses	Drs. Young, Thamban, and Dobbie	\$731	\$2,193
Develop standard work and staff education	Review and update process for handling CII sale and documentation (3 pharmacists @\$60/hr, 4 technicians @\$25/hr)	168 hours	\$47,040
Pyxis	Add double tower at South Health – monthly lease	\$35/month	\$420
	Pyxis tower reconfiguration to accommodate additional inventory (1 technician @\$25/hr)	24 hours	\$600
	Pyxis tower reconfiguration to accommodate inventory sold to South Health	6 hours	\$144
Paperwork/file set-ups	Set up filing system, Pyxis delivery reconciliation reports, and Pyxis sales document	8 hours	\$210
DEA 222 form reconciliation	Completion of DEA 222 form for CII sold to SH, Endo, and Surgical LD.	12 hours	\$252
Transportation – Powell Moving	Moving double tower to South Health from BW and moving single tower from South Health to BW	One time Flat fee	\$500
<b>Maintenance Work (annualized expense)</b>			
Deliveries and medication refills	<ul style="list-style-type: none"> <li>Endoscopy - additional 15 minutes on Monday/Wednesday</li> <li>South Pavilion- additional 45 minutes on Tuesday/Thursday/Friday (Refilling of narcotic boxes onsite).</li> <li>Lake Drive additional 1 hour daily (refilling main pyxis with narcotics, refilling other pyxis machines from main supply and refilling narcotic boxes onsite).</li> <li>Additional paper work- 30 minutes/day.</li> </ul>	11 hours per week	\$8,580
Documentation / Filing / Audits	Pharmacy Manager documentation and inventory reconciliation and audits by Pyxis lead technician	12 hours per week	\$26,520



RICK SNYDER  
GOVERNOR

STATE OF MICHIGAN  
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
LANSING

SHELLY EDGERTON  
DIRECTOR

Dear Licensee:

It has come to the Bureau's attention that the controlled substance additional facility license referenced above was issued in error. Automated dispensing machines/devices may be legally operated by a pharmacy at a hospital only if there is a licensed pharmacy at the same address; the machine must be under the control of a licensed pharmacist. In the absence of a licensed pharmacy, a machine may be legally operated at a hospital, or satellite location, under the control of a licensed prescriber: a physician, dentist, podiatrist, veterinarian, or optometrist certified to administer and prescribe therapeutic pharmaceutical agents. The one exception allows a pharmacy to own and control an automated dispensing device at a Long Term Care Facility.

Based on current law the Bureau cannot renew the existing license referenced above as it does not fall within the allowable circumstances. There are 2 options for licensure for the additional facility location above:

- 1) Obtain licensure as a pharmacy.
- 2) Have a prescriber assume control and responsibility of the drugs stored within the machine. Note: Not all prescribers are licensed to dispense prescription medication or controlled substances.

You may visit our website at [www.michigan.gov/bpl](http://www.michigan.gov/bpl) to obtain applications as needed. Please direct any questions for the Bureau to Stacie Bayes at [BPLHelp@michigan.gov](mailto:BPLHelp@michigan.gov) or 517-241-0560.

Sincerely,

Andrew Brisbo, Director  
BPL Licensing Division